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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,022	11/25/2003	Mary Ann Lukas-Laskey	04012.0384	3995

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EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
10/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/721,022	LUKAS-LASKEY ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9,14, 15,17,18,22,23 and 26-30* is/are rejected.

7)☒ Claim(s) *7,8,10-13,16,19-21,24 and 25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Reply filed August 13, 2007 is acknowledged. Claims 1-30 remain under consideration.

The Amendment filed September 14, 2005 proposes amendments to claim 1 and the Amendment filed and March 10, 2006 proposes amendments to claims 7, 9 and 20, respectively, that do not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications. All amendments made to reissue claims must be made using brackets and underlining to show changes relative to the issued patent. A supplemental paper correctly amending the reissue application is required.

Further, a clean copy of all new claims (those not issued in the patent) – with underlining - is required to show that these have been added relative to the issued patent.

In accordance with 37 CFR 1.175(b)(1), if Applicants file an Amendment to the claims or specification, then a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

An example of acceptable language to be used in the supplemental oath/declaration is as follows:

> "Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

See MPEP § 1414.01.

Rejections not reiterated from previous Office Actions are hereby withdrawn.

In the last Office Action claims 1-6, 14, 15, 17, 18, 22, 23 and 26-30 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written

description requirement. It was asserted the claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The recitation in claims 1, 14, 17, 22, 26 and 27 "maintenance period is greater than six months" is new matter. The recitation "to statistically decrease the risk of mortality caused by congestive heart failure" in claims 12, 15, 18, 23 and 28 is new matter.

Applicants have initially requested an explanation directed to the timing and the practice of setting forth a rejection directed to a claim that had previously been allowed by the Examiner.

A reissue application is examined in the same manner as a non-reissue, non-provisional application. It is subject to all the requirements of the rules related to non-reissue applications. 37 CFR 1.176 provides that an original claim, if re-presented in a reissue application, will be fully examined in the same manner, and subject to the same rules as if being presented for the first time.

Further, according to MPEP 706.04, a claim noted as allowable shall thereafter be rejected only after the proposed rejection has been submitted to the primary Examiner for consideration of all the facts and approval of the proposed Action. That rule is applicable to the present case.

With respect to the new matter rejection of record, Applicants argue no reasons have been provided why a person skilled in the art at the time the application was filed

would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed.

More specifically, concerning the recitation "maintenance period is greater than six months," Applicants argue at column 5, lines 21-35 and 40-63, column 6, lines 1-24, column 7, lines 46-59, evidence that an open-ended maintenance phase beyond the specified 6 to 12 months was contemplated and disclosed by the inventors. Applicants urge a person of ordinary skill would further have understood the maintenance phase *could be* an on-going treatment and a literal description of claimed subject matter need not be present.

Concerning the recitation "to statistically decrease the risk of mortality caused by congestive heart failure," Applicants argue the measure of mortality risk is necessarily statistical due to the nature of the treatment and the measure of mortality in terms of patient deaths and refer to column 3, lines 49-63, in the '821 Patent. Applicants urge the nature of the referenced mortality risk reduction as being a statistical reduction is both express and implicit in the nature of the measure of mortality based on patient deaths and *ipsis verbis* support is not required.

Applicants' arguments have been given careful consideration but are not found persuasive. The rejection of record of claims 1-6, 14, 15, 17, 18, 22, 23 and 26-30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained. Both of the recitations, "maintenance period is greater than six months" and "to statistically decrease the risk of mortality caused by congestive heart failure," recite subject matter that is broader in scope than that provided by the

instant specification. Methods of administration that *could* occur, or are subject to interpretation, or are implicit in nature, are not herein at issue. The referenced protocols do not correlate with the recited limitations in each of the present claims with respect to a "maintenance period." The specification fails to provide statistical support for each of the claimed methods with respect to dosages and dosing regimens.

The rejection of claim 9 under 35 U.S.C. 102(a), as being anticipated by Metra et al. Journal of the American College of Cardiology, was maintained in the last Office Action. It was asserted Metra teaches the oral administration of 6.25 mg of carvedilol twice a day for 7 days. See the Abstract under *Methods*. Metra teaches the addition of carvedilol to "standard therapy", which meets the limitation of claim 9 drawn to "in combination with at least one other therapeutic agent". The open language of claim 9, i.e., the recitation of "comprising," allows for the inclusion of additional therapeutic options.

Concerning definition of decreasing "a risk of mortality", Applicants argue a hybrid definition of "mortality" has been applied. To support this position, Applicants have provided four documents which have been considered by the Examiner:

(A)
Stedman's Medical Dictionary, 26th Ed. (1995), pg 1054;
(B)
Applefeld, M.M., (1986) Am. J. Med., 80, Suppl. 2B, 73-77;
(C)
Waagstein, The Lancet, 342 (1993), 1441-1446; and
(D) The Cardiac Insufficiency Bisoprolol Study (CIBIS), Circulation, 90, No. 4 (1994), 1765-1773.

In view of the references cited *supra*, Applicants argue the interpretation of decreasing a risk of mortality by encompassing the hemodynamic and symptomatic

effects attributed to Metra is inconsistent with Applicants' use of "mortality" when describing mortality studies. Applicants urge the present specification discloses an equivalence of "reduction in risk of death" and "reduction in the mortality."

As clearly stated on page 10 of the last Office Action, reducing the risk of mortality relates to the qualities and conditions of being liable or subject to death, as well as death rate. Further, **the present claims fail to recite a "rate."**

Because the broadest reasonable interpretation of the claim is consistent with the instant specification, the rejection of record of claim 9, as being anticipated by Metra et al. Journal of the American College of Cardiology, is maintained. Since improvement of hemodynamic and symptomatic parameters that define congestive heart failure is demonstrated by Metra, a reduction in a risk of mortality occurs.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel can be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

September 27, 2007

Phyllis G. Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER